IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of

Inventor(s):	Delcomyn, et al.
Title:	CHEMICAL AND BIOLOGICAL WARFARE AGENT DECONTAMINATING METHODS USING DIOXIRANE-PRODUCING FORMULATIONS
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Commissioner for Patents
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RULE 132 DECLARATION OF INVENTOR CARRIE DELCOMYN

I, Carrie Delcomyn, hereby declare as follows:

1. Applied Research Associates, Inc., has developed a pH neutral (pH 5-9), dioxirane generating formulation, capable of neutralizing chemical and biological substrates, which is the subject matter of the above identified application, of which I am an inventor.

2. I am familiar with the U.S. Patent issued to McNeil (US 5,403,549), which was cited in the present application, and which presents dioxirane-generating bactericide/sporicide formulations.

3. McNeil is generally silent as to the pH of his dioxirane-generating formulations, but presents several examples in which he expressly states that the inclusion of a significant amount of buffer hinders the bactericidal/sporicidal activity of his formulations (see Example 1, Samples A-5, B-24 and B-30; Example 2, Sample E-07; Example 3, Samples C-12 and C-14; and Example 4, C-14A).

4. McNeil is only able to develop a few compositions in which the inclusion of a buffer does not inhibit the bactericidal / sporicidal effectiveness of his dioxirane formulation, using a small

amount (1%) of his buffer solution, 0.5M KH_2PO_4, pH 7.4 (see Example 2, Samples C-02 and C-03), and using Potassium biphthalate, pH 4.0 (see Example 4, Sample C-15N).

5. Because McNeil does not reference the pH of his formulations, Applied Research Associates, Inc., under my direction, formulated several of the McNeil compositions to determine the pH thereof, including those where the buffer did, and where the buffer did not, inhibit the bactericidal and sporicidal activity of the dioxirane.

6. McNeil prepared his test solutions (described in Col. 10, Lines 13-41) as follows:

(a) Caroate was weighed in a tared 5 ml vial and ketone was weighed in a 30 ml screw-cap vial;

(b) Water or buffer solution was added to the vial containing the ketone to make 10 g samples; and

(c) The solutions were activated by adding the pre-weighed caroate to the aqueous ingredients in the 30 ml vial at room temperature, agitating the resulting mixture, and allowing the sample to stand for 10 minutes at room temperature

7. McNeil describes his formulations in the examples by a caroate/ketone molar ratio, and percents of caroate and ketone, buffer, and water in the total solution (see McNeil, Cols. 11-12, Tables 1-4). In McNeil's examples, the percentage of caroate, ketone, buffer and water in the total solution always sum to 100%.

8. McNeil describes his source of caroate (potassium peroxymonosulfate; $KHSO_5$) as Oxone ($2KHSO_5.KHSO_4.K_2SO_4$) (Col. 10, Lines 23-28)[1]. Oxone comprises potassium peroxymonosulfate (caroate) and other compounds; however, McNeil only references caroate in his examples, and omits any reference to the presence of the other Oxone compounds in his formulations. Thus, it is not clear

[1] $KHSO_5$ has a formula weight of 152 g/mole; Oxone's formula weight is 614 g/mole.

whether McNeil's reference to caroate in his sample formulations is the caroate compound of Oxone (in which case the remaining compounds of Oxone are unaccounted for or ignored in the McNeil examples because the total sum of caraoate, ketone, buffer and water equal 100%), or if he is referencing Oxone as the caroate, disregarding the fact that Oxone comprises compounds in addition to potassium peroxymonosulfate.

9. In preparing the McNeil formulations for testing, we first prepared a 50 mL stock buffer solution of 0.5M KH_2PO_4, pH 7.4, using 3.4 g KH_2PO_4[2], bringing the solution to 50 mL volume with deionized water, and adding sodium hydroxide to adjust the pH to 7.4.

10. We then prepared the McNeil formulations for pH testing, as follows:

(a) The ketone was weighed in a vial;

(b) The stock buffer solution prepared above, and/or deionized water were added to the vial, to make a 10 g solution; and

(c) Oxone was added to the vial at room temperature, resulting mixture was agitated, and allowed to stand for 10 minutes.

11. As discussed above, McNeil is silent as to whether the molar ratio of caroate to ketone, and the percent of caroate and ketone in solution, in his examples refers to potassium peroxymonosulfate or Oxone as the caroate. Therefore, in some formulations we included sufficient Oxone so that the potassium peroxymonosulfate (and ketone) therein satisfied the caroate/ketone molarity and percentage of solution specifications of McNeil; in these solutions we ignored the additional compounds of Oxone in the element weight percentages. In other formulations we included sufficient Oxone so that the Oxone (and ketone) satisfied the caroate/ketone molarity and

[2] The formula weight of KH_2PO_4 = 136.09 g/mol; thus, to create a 0.5M solution, we used 3.4g KH_2PO_4 diluted to 50 mL. 136.09 g/mole * 0.5 moles/L = 68.045 g/L = 6.8045 g/100 mL = 3.4 g/50 mL

percentage of solution specifications, without acknowledging that Oxone includes compounds in addition to potassium peroxymonosulfate. For purposes of generating formulations, it is important to note that Oxone (formula weight of 614 g/mol) comprises 42.8 % (minimum per manufacturer) - 49.5% (maximum theoretical) w/w potassium peroxymonosulfate.